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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,652	10/30/2000	Edgar B. Cahoon	BB1168 US NA	8593

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[REDACTED] EXAMINER

MCELWAIN, ELIZABETH F

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1638

DATE MAILED: 01/15/2003 /S/

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/699,652	CAHOON ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 October 2002 and 08 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-21,25-29 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-21,25-29 and 38-40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

The amendment filed October 1, 2002 has been entered.

Claims 22, 23, 24 and 30-37 are cancelled.

Claims 16-21, 25-27 and 35-39 are amended.

Claim 40 is newly submitted.

5 The supplemental amendment filed October 8, 2002 has been entered.

Claims 16, 20 and 21 have been twice amended.

Applicant's election without traverse of Group I, claims 16-29, 38 and 39 in Paper No.

10 is acknowledged. Applicant also elected to prosecute the sequences of SEQ ID NO: 11 and

12. However, the amendment filed October 8, 2002 amended the claims to delete SEQ ID NO:

10 11 and 12, and to substitute SEQ ID NO: 13 and 14. Therefore, the elected invention that is examined is Group I and the sequences of SEQ ID NO: 13 and 14.

Claims 16-29 and 38-40 are examined in the present office action.

35 U.S.C. 101 reads as follows:

15 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-29 and 38-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility, a credible asserted utility or a well established utility.

Claims 16-29 and 38-40 are drawn to a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO:13 encoding SEQ ID NO: 14, and the specification states (at page 8) that this sequence is a triacylglycerol lipase. However, the specification does not provide any evidence to support the claim that this sequence would have triacylglycerol lipase activity. While the specification discloses methods for transforming plants with sequences and analyzing for seed oil fatty acids, there is no indication that any of these plants were transformed with the sequence that is claimed and had modified triacylglycerol. The only specific utility provided for the claimed sequence is for use as a triacylglycerol lipase. However, this utility is not supported by the mere disclosure of SEQ ID NO: 13 and 14 and unsupported assertion that it has triacylglycerol lipase activity.

Claims 16-29 and 38-40 are also rejected under 35 U.S.C. 112, first paragraph.
Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 16-29 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 16-29 and 38-40 are drawn to a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO: 13 and to sequences encoding SEQ ID NO: 14 or at least 80% identical to SEQ ID NO: 14 , and encoding a triacylglycerol lipase. However, the specification does not provide any evidence to support the assertion that this sequence would have triacylglycerol lipase activity, as stated above. Even if a sequence was known that has similarity to the claimed sequence, it is well established that sequence similarity is not sufficient to determine functionality of a DNA coding sequence. See the teachings of Doerks (TIG 14, no. 6: 10 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, 15 Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different 20 molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a specific activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other 5 sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the 10 functionality or more knowledge of the particular structural features that are required for conferring this function. Therefore, it would require undue experimentation to establish how to use the claimed sequence, given the uncertainty of predicting the activity of an enzyme from a specific amino acid sequence, as stated above; the absence of guidance with regard to what amino acid sequences would confer triacylglycerol lipase activity; the lack of working 15 examples that the claimed sequence encodes a triacylglycerol lipase; and given the high level of skill in the art and the state of the prior art, which did not teach what structural elements are required to obtain a sequence encoding a triacylglycerol lipase gene.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Tiffiany Tabb, whose telephone number is (703) 605-1238, or to the Group receptionist whose telephone number is (703) 308-0196.

10 Elizabeth F. McElwain, Ph.D.
January 13, 2003

Elizabeth F. McElwain
ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600